IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Denise Faustman

Confirmation No.: 1752

Serial No.:

10/577,891

Art Unit:

1644

Filed:

December 14, 2006

Examiner:

Michail A. Belyavskyi

Customer No.:

21559

Title:

METHODS OF ORGAN REGENERATION

INFORMATION DISCLOSURE STATEMENT

Applicant submits the references listed on the enclosed Form PTO-1449, copies of which are enclosed, with the exception of U.S. patents and U.S. patent application publications. Copies of search reports from corresponding international applications are also enclosed.

Submission of this statement is not a representation that a search has been made, nor is the inclusion of information in this statement an admission that the information is material to patentability.

This statement is being filed before the receipt of a first Office action on the merits.

If there are any other charges or any credits, please apply them to Deposit Account

No. 03-2095.

Respectfully submitted,

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TODD ARMSTRONG, Ph.D. Rig. No. 54,590

Date: 18 June 2007

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00786/405004 Attorney Docket No. U.S. DEPARTMENT OF COMMERCE SUBSTITUTE FORM PTO-1449 PATENT AND TRADEMARK OFFICE (MODIFIED) Serial No. 10/577,891 Denise Faustman Applicant INFORMATION DISCLOSURE December 14, 2006 Filing Date STATEMENT BY APPLICANT (Use several sheets if necessary) Group 1644 July 2, 2007 **IDS Filed** (37 C.F.R. § 1.98(b))

U.S. PATENT DOCUMENTS			IT DOCUMENTS
Examiner's Document Publication Initials Number Date			Patentee or Applicant
	4,309,418	01/05/1982	Green
	4,457,916	07/03/1984	Hayashi et al.
	4,495,282	01/22/1985	Ohnishi et al.
	4,677,063	06/30/1987	Mark et ål.
	4,677,064	06/30/1987	Mark et al.
	4,681,760	07/21/1987	Fathman
	4,791,101	12/13/1988	Adolf
	4,816,567	03/28/1989	Cabilly et al.
	4,879,226	11/07/1989	Wallace et al.
	4,963,354	10/16/1990	Shepard et al.
	4,985,241	01/15/1991	Zimmerman et al.
	5,002,876	03/26/1991	Sreekrishna et al.
	5,059,530	10/22/1991	Oshima et al.
	5,139,481	08/18/1992	Faustman et al.
	5,215,743	06/01/1993	Singh et al.
	5,283,058	02/01/1994	Faustman
	5,288,852	02/22/1994	Yamada et al.
	5,487,984	01/30/1996	Allet et al.
	5,538,854	07/23/1996	Faustman
	5,560,908	10/01/1996	Satoh et al.
	5,593,698	01/14/1997	Weiner et al.

EXAMINER	DATE CONSIDERED
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SUBSTITUTE FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	00786/405004
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		Group	1644
(37 C.F.R. § 1.98(b))		IDS Filed	July 2, 2007

U.S. PATENT DOCUMENTS			
5,783,216	07/21/1998	Faustman	
5,821,337	10/13/1998	Carter et al.	
5,843,425	12/01/1998	Sachs et al.	
5,843,452	12/01/1998	Wiedmann et al.	
5,874,306	02/23/1999	Beattie et al.	
6,056,952	05/02/2000	Rosenberg	
6,284,879	09/04/2001	Faustman	
6,414,218	07/02/2002	Faustman et al.	
6,491,908	12/10/2002	Rosenberg	
6,599,710	07/29/2003	Faustman	
6,617,171	09/09/2003	Faustman et al.	
6,660,487	12/09/2003	Faustman	
6,773,705	08/10/2004	Faustman et al.	
6,844,011	01/18/2005	Faustman	
6,866,843	03/15/2005	Habener et al.	
6,923,959	08/02/2005	Habener et al.	
6,984,380	01/10/2006	Faustman	
2002/0106689	08/08/2002	Faustman et al.	
2002/0123472	09/05/2002	Faustman	
2003/0005469	01/02/2003	Faustman et al.	
2003/0031657	02/13/2003	Habener et al.	
2004/0028658	02/12/2004	Faustman	
2004/0031066	02/12/2004	Faustman et al.	

EXAMINER

DATE CONSIDERED

	SUBSTITUTE FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	00786/405004
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U.S. PATENT DOCUMENTS			
2004/0229785 11/18/2004		Faustman	
2005/0158302	07/21/05	Faustman et al.	
2005/0158288	07/21/05	Faustman	
2005/0244386	11/03/05	Habener et al.	
2006/0062769	03/23/2006	Habener et al.	
2007/0116688	05/24/2007	Faustman	

	FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION				
Examiner's Initials	Document Number	Country or Patent Office	Translation (Yes/No)		
	WO 95/24914	09/21/1995	WIPO		
	WO 95/25533	09/28/1995	WIPO		
	WO 97/08328	03/06/1997	WIPO		
	WO 00/53209	9/14/2000	WIPO		

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)			
	Aldrich et al., "Positive Selection of Self- and Alloreactive CD8* T Cells in <i>Tap-1</i> Mutant Mice," <i>Proc. Natl. Acad. Sci. USA</i> 91:6525-6528 (1994). Alison et al., "Hepatocytes from Non-Hepatic Adult Stem Cells," <i>Nature</i> 406:257 (2000). Allen et al., "Effect of Bacillus Calmette-Guerin Vaccination on New-Onset Type 1 Diabetes," <i>Diabetes Care</i> 22:1703-1707 (1999). Altomonte et al., "Serum Levels of Interleukin-1b, Tumour Necrosis Factor-a and Interleukin-2 in Rheumatoid Arthritis. Correlation with Disease Activity," <i>Clin. Rheumatol.</i> 11:202-205 (1992).		
	Anderson et al., "Can Stem Cells Cross Lineage Boundaries?" Nat. Med. 7:393-395 (2001).		
EXAMINER	EXAMINER DATE CONSIDERED		

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication of considered. ONSIDERED EXCEPT WHERE LINED THROUGH. /MB/

SUBSTITUTE FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	00786/405004
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(37 C.F.R. § 1.98(b))		IDS Filed	July 2, 2007

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)
Anderson et al., "Studies on the Cytophilic Properties of Human β ₂ Microglobulin," <i>J. Immunol.</i> 114:997-1000 (1975).
Aristarkhov et al., "E2-C, a Cyclin-Selective Ubiquitin Carrier Protein Required for the Destruction of Mitotic Cyclins," <i>Proc. Natl. Acad. Sci. USA</i> 93:4294-4299 (1996).
Ashton-Rickardt et al., "Evidence for a Differential Avidity Model of T Cell Selection in the Thymus," Cell 76:651-663 (1994).
Ashton-Rickardt et al., "Peptide Contributes to the Specificity of Positive Selection of CD8* T Cells in the Thymus," Cell 73:1041-1049 (1993).
Atkinson et al., "The NOD Mouse Model of Type 1 Diabetes: As Good as it Gets?" Nat. Med. 5:601-604 (1999).
Baeuerle and Baltimore, "NF- _k B: Ten Years After, " <i>Cell</i> 87:13-20 (1996).
Baeza et al., "Pancreatic Regenerating Gene Overexpression in the Nonobese Diabetic Mouse During Active Diabetogensis," <i>Diabetes</i> 45:67-70 (1996).
Baeza et al., "Reg Protein: A Potential Beta-Cell-Specific Growth Factor?" Diabetes Metab. 22:229-234 (1996).
Baeza et al., "Specific Reg II Gene Overexpression in the Non-Obese Diabetic Mouse Pancreas During Active Diabetogenesis," <i>FEBS Letters</i> 416:364-368 (1997).
Baldwin, "The NF-κB and IκB Proteins: New Discoveries and Insights," <i>Ann. Rev. Immunol.</i> 14:649-683 (1996).
Barres, "A New Role for Glia: Generation of Neurons!" Cell 97:667-670 (1999).
Beg et al., "An Essential Role for NF-κB in Preventing TNFα-Induced Cell Death," Science 274:782-784 (1996).
Bendelac et al., "Syngeneic Transfer of Autoimmune Diabetes from Diabetic NOD Mice to Healthy Neonates," <i>J. Exp. Med.</i> 166:823-832 (1987).
Bernabeu et al., "β₂ -Microglobulin from Serum Associates with MHC Class I Antigens on the Surface of Cultured Cells," <i>Nature</i> 308:642-645 (1984).
Bjornson et al., "Turning Brain into Blood: A Hematopoietic Fate Adopted by Adult Neural Stem Cells <i>In Vitro</i> ," <i>Science</i> 283:534-537 (1999).
Brayer et al., "Alleles from Chromosomes 1 and 3 of NOD Mice Combine to Influence Sjögren's Syndrome-Like Autoimmune Exocrinopathy," <i>J. Rheumatol.</i> 27:1896-1904 (2000).

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	EXAMINER	DATE CONSIDERED

SUBSTITUTE FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	00786/405004
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(37 C.F.R. § 1.98(b))		IDS Filed	July 2, 2007

	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)
	Brazelton et al., "From Marrow to Brain: Expression of Neuronal Phenotypes in Adult Mice," Science 290:1775-1779 (2000).
	Brod et al., "Ingested Interferon α Suppresses Type I Diabetes in Non-Obese Diabetic Mice," <i>Diabetologia</i> 41: 1227-1232 (1998).
	Bunting et al., "Enforced P-glycoprotein Pump Function in Murine Bone Marrow Cells Results in Expansion of Side Population Stem Cells In Vitro and Repopulating Cells In Vivo," <i>Blood</i> 96:902-909 (2000).
	Chatenoud et al., "CD3 Antibody-Induced Dominant Self Tolerance in Overtly Diabetic NOD Mice," <i>J. Immunol.</i> 158:2947-2954 (1997).
	Colucci et al., "Programmed Cell Death in the Pathogenesis of Murine IDDM: Resistance to Apoptosis Induced in Lymphocytes by Cyclophosphamide," <i>J. Autoimmunity</i> 9:271-276 (1996).
	Corbett et al., "Nitric Oxide Mediates Cytokine-Induced Inhibition of Insulin Secretion by Human Islets of Langerhans" <i>Proc. Natl. Acad. Sci. USA</i> 90:1731-1735 (1993).
	Coux et al., "Enzymes Catalyzing Ubiquitination and Proteolytic Processing of the p105 Precursor of Nuclear Factor κΒ1," <i>J. Biol. Chem.</i> 273:8820-8828 (1998).
	Dilts et al., "Autoimmune Diabetes: The Involvement of Benign and Malignant Autoimmunity," <i>J. Autoimmun.</i> 12:229-232 (1999).
	Driscoll et al., "The Proteasome (Multicatalytic Protease) is a Component of the 1500-kDa Proteolytic Complex Which Degrades Ubiquitin-Conjugated Proteins," <i>J. Biol. Chem.</i> 265:4789-4792 (1990).
	Eglitis et al., "Hematopoietic Cells Differentiate into Both Microglia and Macroglia in the Brains of Adult Mice," Proc. Natl. Acad. Sci. USA 94:4080-4085 (1997).
	Eytan et al., "ATP-Dependent Incorporation of 20S Protease into the 26S Complex that Degrades Proteins Conjugated to Ubiquitin," <i>Proc. Natl. Acad. Sci. USA</i> 86:7751-7755 (1989).
	Fan et al., "Generation of p50 Subunit of NF-κB by Processing of p105 Through an ATP-Dependent Pathway," Nature 354:395-398 (1991).
	Faustman et al., "Abnormal T-Lymphocyte Subsets in Type Diabetes," Diabetes 38:1462-1468 (1989).
	Faustman et al., "Linkage of Faulty Major Histocompatibility Complex Class I to Autoimmune Diabetes," Science 254:1756-1761 (1991).
	Faustman et al., "Murine Pancreatic β-Cells Express H-2K and H-2D but not la Antigens," <i>J. Exp. Med.</i> 151:1563-1568 (1980).
L	

EXAMINER	DATE CONSIDERED

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		Applicant Filing Date	Denise Faustman December 14, 2006
		Group	1644
(37 C.F.R. § 1.98(b))		IDS Filed	July 2, 2007

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)
Faustman et al., "Prevention of Xenograft Rejection by Masking Donor HLA Class I Antigens," Science 252:1700-1702 (1991).
Faustman et al., "T-Lymphocyte Changes Linked to Autoantibodies. Association of Insulin Autoantibodies with CD4+CD45R* Lymphocyte Subpopulation in Prediabetic Subjects," <i>Diabetes</i> 40:590-597 (1991).
Feldman et al., "Anti-TNF α Therapy is Useful in Rheumatoid Arthritis and Crohn's Disease: Analysis of the Mechanism of Action Predicts Utility in Other Diseases," <i>Transplant. Proc.</i> 30:4126-4127 (1998).
Foulis, "C.L. Oakley Lecture (1987). The Pathogenesis of Beta Cell Destruction in Type I (Insulin-Dependent) Diabetes Mellitus," <i>J. Pathol.</i> 152:141-148 (1987).
Fu et al., "Antigen Processing and Autoimmunity: Evaluation of mRNA Abundance and Function of HLA-Linked Genes," Ann. NY Acad. Sci. 842:138-155 (1998).
Fu et al., "Defective Major Histocompatibility Complex Class I Expression on Lymphoid Cells in Autoimmunity," <i>J. Clin. Invest.</i> 91:2301-2307 (1993).
Gage, "Mammalian Neural Stem Cells," Science 287:1433-1438 (2000).
Gage et al., "Multipotent Progenitor Cells in the Adult Dentate Gyrus," J. Neurobiol. 36:249-266 (1998).
Ganoth et al., "A Multicomponent System that Degrades Proteins Conjugated to Ubiquitin. Resolution of Factors and Evidence for ATP-Dependent Complex Formation," <i>J. Biol. Chem.</i> 263:12412-12419 (1988).
Gaur et al., "Induction of Islet Allotolerance in Nonhuman Primates," Ann. NY Acad. Sci. 958:199-203 (2002).
Gazda et al., "Diabetes Results from a Late Change in the Autoimmune Response of NOD Mice," <i>J. Autoimmun</i> . 10:261-270 (1997).
Ghosh et al., "Activation <i>In Vitro</i> of NF-κB by Phosphorylation of its Inhibitor I κ B," <i>Nature</i> 344:678-682 (1990).
Glas et al., "The CD8+ T Cell Repertoire in β_2 -Microglobulin-Deficient Mice Is Biased towards Reactivity Against Self-Major Histocompatibility Class I," <i>J. Exp. Med.</i> 179:661-672 (1994).
Goldberg, "Functions of the Proteasome: The Lysis at the End of the Tunnel," Science 268:522-523 (1995).
Graves et al., "Lack of Association Between Early Childhood Immunizations and β-Cell Autoimmunity," <i>Diabetes Care</i> 22:1694-1967 (1999).

EXAMINER DATE CONSIDERED

SUBSTITUTE FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	00786/405004
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		Group	1644
(37 C.F.R. § 1.98(b))		IDS Filed	July 2, 2007

	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)
	ohansson et al., "Identification of a Neural Stem Cell in the Adult Mammalian Central Nervous System," <i>Cell</i> 6:25-34 (1999).
Ji D	uang et al., "Beneficial Influence of Glycemic Control Upon the Growth and Function of Transplanted Islets," liabetes 43:1334-1339 (1994).
K	anzler and Dear, "Hox11 Acts Cell Autonomously in Spleen Development and Its Absence Results in Altered cell Fate of Mesenchymal Spleen Precursors," Devel. Biol. 234:231-243 (2001).
K	aufman et al., "Patterns of Hemopoietic Reconstitution in Nonobese Diabetic Mice: Dichotomy of Allogeneic desistance Versus Competitive Advantage of Disease-Resistant Marrow," <i>J. Immunol.</i> 158:2435-2442 (1997).
	awaski et al., "Prevention of Type 1 Diabetes: from the View Point of β Cell Damage," <i>Diabetes Res. Clin.</i> Pract. 66:S27-S32 (2004).
	ileran et al., "The DNA Binding Subunit of NF- κB is Identical to Factor KBF1 and Homologous to the <i>rel</i> oncogene Product," <i>Cell</i> 62:1007-1018 (1990).
К	Сорр and Ghosh, "Inhibition of NF-кВ by Sodium Salicylate and Aspirin," <i>Science</i> 265:956-959 (1994).
	rause et al., "Multi-Organ, Multi-Lineage Engraftment by a Single Bone Marrow-Derived Stem Cell," <i>Cell</i> 05(3):369-377 (2001).
к	Guehnle and Goodell, "The Therapeutic Potential of Stem Cells from Adults," <i>BMJ</i> 325:372-376 (2002).
	won et al., "Evidence for Involvement of the Proteasome Complex (26S) and NF κB in IL-1β-induced Nitric Diabetes and Prostaglandin Production by Rat Islets and RINm5F Cells" <i>Diabetes</i> 47:583-591 (1998).
K	Kwon et al., "Interleukin-1β -Induced Nitric Oxide Synthase Expression by Rat Pancreatic β-Cells: Evidence for the Involvement of Nuclear Factor κB in the Signaling Mechanism," <i>Endocrinology</i> 136:4790-4795 (1995).
	ahav-Baratz et al., "Reversible Phosphorylation Controls the Activity of Cyclosome-Associated Cyclin-Ubiquitin.igase," <i>Proc. Natl. Acad. Sci. USA</i> 92:9303-9307 (1995).
	akey et al., "BCG Immunotherapy Prevents Recurrence of Diabetes in Islet Grafts Transplanted into Spontaneously Diabetic NOD Mice," <i>Transplantation</i> 57:1213-1217 (1994).
	ammert et al., "Induction of Pancreatic Differentiation by Signals from Blood Vessels," <i>Science</i> 294:564-567 2001).
	anza et al., "Transplantation of Encapsulated Canine Islets into Spontaneously Diabetic BB/Wor Rats Without mmunosuppression," <i>Endocrinology</i> 131:637-642 (1992).

	1
EXAMINER	DATE CONSIDERED

SUBSTITUTE FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	00786/405004
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(37 C.F.R. § 1.98(b))		IDS Filed	July 2, 2007

	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)
	Lapchak et al., "Tumor Necrosis Factor Production is Deficient in Diabetes-Prone BB Rats and Can be Corrected by Complete Freund's Adjuvant: A Possible Immunoregulatory Role of Tumor Necrosis Factor in the Prevention of Diabetes," Clin. Immunol. Immunopathol. 65:129-134 (1992).
	Lawrence et al., "Differential Hepatocyte Toxicity of Recombinant Apo2L/TRAIL Versions," <i>Nat. Med.</i> 7:383-385 (2001).
	Li and Faustman, "Use of Donor β₂-Microglobulin-Deficient Transgenic Mouse Liver Cells for Isografts, Allografts, and Xenografts," <i>Transplantation</i> 55:940-946 (1993).
	Li et al., "Abnormal Class I Assembly and Peptide Presentation in the Nonobese Diabetic Mouse," <i>Proc. Natl. Acad. Sci. USA</i> 91:11128-11132 (1994).
	Li et al., "Reduced Expression of Peptide-Loaded HLA Class I Molecules on Multiple Sclerosis Lymphocytes," Ann. Neurol. 38:147-154 (1995).
-	Ljunggren et al., "MHC Class I Expression and CD8* T Cell Development in TAP1/β2-Microglobulin Double Mutant Mice," <i>Int. Immunol.</i> 7:975-984 (1995).
	Macchi et al., "Impaired Apoptosis in Mitogen-Stimulated Lymphocytes of Patients with Multiple Sclerosis," NeuroReport 10:399-402 (1999).
	Markiewicz et al., "Long-Term T Cell Memory Requires the Surface Expression of Self-Peptide/Major Histocompatibility Complex Molecules," <i>Proc. Natl. Sci. USA</i> 95:3065-3070 (1998).
	Markmann et al., "Indefinite Survival of MHC Class I-Deficient Murine Pancreatic Islet Allografts," Transplantation 54:1085-1089 (1992).
	Marriott BJ, "TNF-α Antagonists: Monoclonal Antibodies, Soluble Receptors, Thalidomide and Other Novel Approaches," <i>Expert Opin. Investig. Drugs</i> 6:1105-1108 (1997).
	Matsumoto et al., "Liver Organogenesis Promoted by Endothelial Cells Prior to Vascular Function," Science 294:559-563 (2001).
	Mayer -Proschel et al., "Isolation of Lineage-Restricted Neuronal Precursors from Multipotent Neuroepithelial Stem Cells," <i>Neuron</i> 19:773-785 (1997).
	McInerney et al., "Prevention of Insulitis and Diabetes Onset by Treatment with Complete Freund's Adjuvant in NOD Mice," <i>Diabetes</i> 40:715-725 (1991).
	McKay et al., "Mammalian Deconstruction for Stem Cell Reconstruction," Nat. Med. 6:747-748 (2000).
	Mercurio et al., "p105 and p98 Precursor Proteins Play an Active Role in NF-κ B-Mediated Signal Transduction," <i>Genes Dev.</i> 7:705-718 (1993).
	Mestas et al., "Of Mice and Not Men: Differences between Mouse and Human Immunology," <i>J. Immunol.</i> 172:2731-2738 (2004).

EXAMINER	DATE CONSIDERED

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant

SUBSTITUTE FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	00786/405004
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(37 C.F.R. § 1.98(b))		IDS Filed	July 2, 2007

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)
Mezey et al., "Turning Blood into Brain: Cells Bearing Neuronal Antigens Generated <i>In Vivo</i> from Bone Marrow," <i>Science</i> 290:1779-1782 (2000).
Miller et al., "Both the Lyt-2+ and L3T4+ T Cell Subsets are Required for the Transfer of Diabetes in Nonobese Diabetic Mice," <i>J. Immunol.</i> 140:52-58 (1988).
Mittleman et al., "A Phase I Pharmacokinetic Study of Recombinant Human Necrosis Factor Administered by a 5 -Day Continuous Infusion," <i>Invest. New Drugs</i> , 10:183-190 (1992).
Miyazaki et al., "Predominance of T Lymphocytes in Pancreatic Islets and Spleen of Pre-Diabetic Non-Obese (NOD) Mice: A Longitudinal Study," <i>Clin. Exp. Immunol.</i> 60: 622-630 (1985).
Morrison, "Stem Cell Potential: Can Anything Make Anything?" Curr. Biol. 11:R7-R9 (2001).
Nomikos et al., "Combined Treatment with Nicotinamide and Desferrioxamine Prevents Islet Allograft Destruction in NOD Mice," <i>Diabetes</i> 35:1302-1304 (1986).
Offield et al., "PDX-1 Is Required for Pancreatic Outgrowth and Differentiation of the Rostral Duodenum," Development 122:983-995 (1996).
Ono et al., "IDDM in BB Rats. Enhanced MHC Class I Heavy-Chain Gene Expression in Pancreatic Islets," Diabetes 37:1411-1418 (1988).
Osorio et al., "Beta-2 Microglobulin Gene Disruption Prolongs Murine Islet Allograft Survival in NOD Mice," Transplant. Proc. 26:752 (1994).
Palombella et al., "The Ubiquitin-Proteasome Pathway is Required for Processing the NF-кВ1 Precursor Protein and the Activation of NF- к В," <i>Cell</i> 78:773-785 (1994).
Pestano et al., "Inactivation of Misselected CD8 T Cells by CD8 Gene Methylation and Cell Death," Science 284: 1187-1191 (1999).
Petersen et al., "Bone Marrow as a Potential Source of Hepatic Oval Cells," Science 284:1168-1170 (1999).
Pontesilli et al., "Circulating Lymphocyte Populations and Autoantibodies in Non-Obese Diabetic (NOD) Mice: A Longitudinal Study," Clin. Exp. Immunol. 70:84-93 (1987).
Qin et al., "Complete Freud's Adjuvant-Induced T Cells Prevent the Development and Adoptive Transfer of Diabetes in Nonobese Diabetic Mice," <i>J. Immunol.</i> 150:2072-2080 (1993).
Rabinovitch et al., "TNF-α Down-Regulates Type 1 Cytokines and Prolongs Survival of Syngeneic Islet Grafts in Nonobese Diabetic Mice," <i>J. Immunol.</i> 159:6298-6303 (1997).
Rabinovitch et al., "Tumor Necrosis Factor Mediates the Protective Effect of Freund's Adjuvant Against Autoimmune Diabetes in BB Rats," <i>J. Autoimmunity</i> 8:357-366 (1995).

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	EXAMINER	DATE CONSIDERED
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(MODIFIED)		Serial No.	10/577,891
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		Applicant	Denise Faustman
		Filing Date	December 14, 2006
		Group	1644
(37 C.F.R. § 1.98(b))		IDS Filed	July 2, 2007

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)
Ramiya et al., "Reversal of Insulin-Dependent Diabetes Using Islets Generated <i>In Vitro</i> from Pancreatic Stem Cells," <i>Nat. Med.</i> 6:278-282 (2000).
Rietze et al., "Purification of a Plurlpotent Neural Stem Cell from the Adult Mouse Brain," <i>Nature</i> 412:736-739 (2001).
Roberts et al., "Hox11 Controls the Genesis of the Spleen," Nature 368:747-749 (1994).
Robertson et al., "Preservation of Insulin mRNA Levels and Insulin Secretion in HIT Cells by Avoidance of Chronic Exposure to High Glucose Concentrations," <i>J. Clin. Invest.</i> 90:320-325 (1992).
Rosenthal, "Prometheus's Vulture and the Stem-Cell Promise," N. Engl. J. Med. 349:267-274 (2003).
Ryu et al., "Reversal of Established Autoimmune Diabetes by Restoration of Endogenous β Cell Function," <i>J. Clin. Invest.</i> 108:63-72 (2001).
Sadelan et al., "Prevention of Type I Diabetes in NOD Mice by Adjuvant Immunotherapy," <i>Diabetes</i> 39:583-589 (1990).
Sarin et al., "Cytotoxic Effect of TNF and Lymphotoxin on T Lymphoblasts," <i>J. Immunology</i> 151:3716-3718 (1995).
Satoh et al., "Inhibition of Type I Diabetes in BB Rats with Recombinant Human Tumor Necrosis Factor-Alpha," J. Immunol. 145:1395-1399 (1990).
Satoh et al., "Recombinant Human Tumor Necrosis Factor α Suppresses Autoimmune Diabetes in Nonobese Diabetic Mice," <i>J. Clin. Invest.</i> 84:1345-1348 (1989).
Schatz et al., "Defective Inducer T-Cell Function Before the Onset of Insulin-Dependent Diabetes Mellitus," <i>J. Autoimmun.</i> 4:125-136 (1991).
Schmidt <i>et al.</i> , "Interspecies Exchange of β ₂ -Microglobulin and Associated MHC and Differentiation Antigens," <i>Immunogenetics</i> 13:483-491 (1981).
Sears et al., "NF-κB p105 Processing Via the Ubiquitin-Proteasome Pathway," J. Biol. Chem. 273:1409-1419 (1998).
Serrano et al., "Non-HLA Associations with Autoimmune Diseases," Autoimmun. Rev. 5:209-214 (2006).
Serup, "Panning for Pancreatic Stem Cells," Nat. Genet. 25:134-135 (2000).
Serup et al., "Islet and Stem Cell Transplantation for Treating Diabetes," BMJ 322:29-32 (2001).

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	Shehadeh et al., "Effect of Adjuvant Therapy on Development of Diabetes in Mouse and Man," <i>Lancet</i> 343:706-707 (1994).
	Shihabuddin et al., "Adult Spinal Cord Stem Cells Generate Neurons After Transplantation in the Adult Dentate Gyrus," <i>J. Neurosci.</i> 20:8727-8735 (2000).
	Slack, "Stem Cells in Epithelial Tissues," Science 287:1431-1433 (2000).
	Song et al., "Tumor Necrosis Factor-Related Apoptosis-Inducing Ligand (TRAIL) Is an Inhibitor of Autoimmune Inflammation and Cell Cycle Progression," <i>J. Exp. Med.</i> 191:1095-1103 (2000).
	Speiser et al., "Loss of ATP-Dependent Proteolysis with Maturation of Reticulocytes and Erythrocytes," <i>J. Biol. Chem.</i> 257:14122-14127 (1982).
	Sreenan et al., "Increased β-Cell Proliferation and Reduced Mass Before Diabetes Onset in the Nonobese Diabetic Mouse," <i>Diabetes</i> 48:989-996 (1999).
	Stephens et al., "Protection of NIT-1 Pancreatic β-Cells from Immune Attack by Inhibition of NF-κΒ," <i>J. Autoimmun</i> . 10:293-298 (1997).
	Storms et al., "Hoechst Dye Efflux Reveals a Novel CD7+CD34- Lymphoid Progenitor in Human Umbilical Cord Blood," <i>Blood</i> 96:2125-2133 (2000).
	Szdoray et al., "Programmed Cell Death in Rheumatoid Arthritis Peripheral Blood T-Cell Subpopulations Determined by Laser Scanning Cytometry," <i>Lab. Invest.</i> 83:1839-1848 (2003).
	Tartaglia et al, "The Two Different Receptors for Tumor Necrosis Factor Mediate Distinct Cellular Responses," Proc. Natl. Acad. Sci. USA 88:9292-9296 (1991).
	Terada et al., "Bone Marrow Cells Adopt the Phenotype of Other Cells by Spontaneous Cell Fusion," <i>Nature</i> 416:542-545 (2002).
	Toma et al., "Isolation of Multipotent Adult Stem Cells from the Dermis of Mammalian Skin," Nat. Cell. Bio. 3:778-784 (2001).
	Townsley et al., "Dominant-Negative Cyclin-Selective Ubiquitin Carrier Protein E2-C/UbcH10 Blocks Cells in Metaphase," <i>Proc. Natl. Acad. Sci. USA</i> 94:2362-2367 (1997).
	Trowsdale et al., "Sequences Encoded in the Class II Region of the MHC Related to the 'ABC' Superfamily of Transporters," <i>Nature</i> 348:741-744 (1990).
	Ulaeto et al., "A T-Cell Dormant State in the Autoimmune Process of Nonobese Diabetic Mice Treated with Complete Freund's Adjuvant," <i>Proc. Natl. Acad. Sci. USA</i> 89:3927-3931 (1992).
	Van der Kooy et al., "Why Stem Cells?" Science 287:1439-1441 (2000).
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EXAMINER	DATE CONSIDERED
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OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)
Van Nocker et al., "The Multiubiquitin-Chain-Binding Protein Mcb1 is a Component of the 26S Proteasome in Saccharomyces cerevisiae and Plays a Nonessential, Substrate-Specific Role in Protein Turnover," Mol. Cell. Biol. 16:6020-6028 (1996).
Van Noort et al., "Cell Biology of Autoimmune Diseases," Int. Rev. Cytol. 178:127-204 (1998).
Vidal-Puig and Faustman, "Tolerance to Peripheral Tissue Is Transient and Maintained by Tissue-Specific Class I Expression," <i>Transplant. Proc.</i> 26:3314-3316 (1994).
Vogel et al., "Studies Cast Doubt on Plasticity of Adult Cells," Science 295:1989-1991 (2002).
Von Herrath et al., "In Vivo Treatment with a MHC Class I-Restricted Blocking Peptide Can Prevent Virus-Induced Autoimmune Diabetes," <i>J. Immunol.</i> 161:5087-5096 (1998).
Wang et al., "Prevention of Recurrence of IDDM in Islet-Transplanted Diabetic NOD Mice by Adjuvant Immunotherapy," <i>Diabetes</i> 41:114-117 (1992).
Watt et al., "Out of Eden: Stem Cells and Their Niches," Science 287:1427-1430 (2000).
Waxman et al., "Demonstration of Two Distinct High Molecular Weight Proteases in Rabbit Reticulocytes, One of which Degrades Ubiquitin Conjugates," <i>J. Biol. Chem.</i> 262:2451-2457 (1987).
Weissman, "Translating Stem and Progenitor Cell Biology to the Clinic: Barriers and Opportunities," Science 287:1442-1446 (2000).
Weringer et al., "Identification of T Cell Subsets and Class I and Class II Antigen Expression in Islet Grafts and Pancreatic Islets of Diabetic BioBreeding/Worcester Rats," <i>Am. J. Pathol.</i> 132:292-303 (1988).
Wicker et al., "Transfer of Autoimmune Diabetes Mellitus with Splenocytes from Nonobese Diabetic (NOD) Mice," Diabetes 35:855-860 (1986).
Willis et al., "Type 1 Diabetes in Insulin-Treated Adult-Onset Diabetic Subjects," <i>Diabetes Res. Clin. Pract.</i> 42:49-53 (1998).
Winston, "Embryonic Stem Cell Research: The Case For," Nat. Med. 7:396-397 (2001).
Wong et al., "Identification of an MHC Class I-Restricted Autoantigen in Type I Diabetes by Screening an Organ-Specific cDNA Library," <i>Nat. Med.</i> 5:1026-1031 (1999).
Yan et al., "Reduced Expression of <i>Tap1</i> and <i>Lmp2</i> Antigen-Processing Genes in the Nonobese Diabetic (NOD) Mouse Due to a Mutation in Their Shared Bidirectional Promoter," <i>J. Immunol.</i> 159:3068-3080 (1997).

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Ying et al., "Changing Potency by Spontaneous Fusion," <i>Nature</i> 416:545-548 (2002).
Zöller et al., "Apoptosis Resistance in Peripheral Blood Lymphocytes of Alopecia Areata Patients," <i>J. Autoimmunity</i> 23:241-256 (2004).
Zulewski et al., "Multipotential Nestin-Positive Stem Cells Isolated from Adult Pancreatic Islets Differentiate Ex Vivo Into Pancreatic Endocrine, Exocrine, and Hepatic Phenotypes," <i>Diabetes</i> 50:521-533 (2001).